

EFFICACY REVIEW

PRODUCT: SVP7

FILE SYMBOL: 83399-6

DATE: November 12, 2010

DP BARCODE: D383981

DECISION NUMBER: 436849

GLP: N/A

CHEMICAL: Permethrin (36.08%)
Dinotefuran (4.95%)
Pyriproxyfen (0.44%)

CHEMICAL NUMBER: Permethrin.....109701
Dinotefuran.....044312
Pyriproxyfen....129032

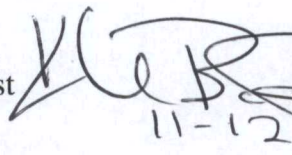
PURPOSE: Review of revised label per Agency review dated October 4, 2010 and rebuttal to required "fly strike" revisions.

MRID: N/A

TEAM REVIEWER: Rita Kumar

EFFICACY REVIEWER: Kable Bo Davis, M.S., Entomologist

BACKGROUND:



A rebuttal to an Agency efficacy review (D380592; 436849), dated October 4, 2010, and the corresponding label were submitted to the Agency on November 11, 2010. The following recommendations apply.

RECOMMENDATIONS:

Fly Strike Rebuttal

1. On pages 11 and 12 of the label, delete the following claims: "*Prevents fly strike*", "*Control fly strike*" and "*Reduces biting fly strike*". The claim "*Kills biting flies that may transmit fly strike.*" is acceptable.

Review of Revised Label

1. Per comment #4 on the Agency review dated October 4, 2010; all references to “mites” must be revised to read “mites (excluding mange mites)”. Specifically, the following claims must be revised. Alternatively, all mite claims may be deleted from the label.
 - a. On page 1, revise “*Mites*” to read “*Mites (excluding mange mites)*”.
 - b. On page 4, revise “*For treatment control and prevention of adult and immature flea stages, ticks, mosquitoes, lice, mites and biting & sand flies (all) year-round treatment is recommended.*” to read “*For control and prevention of ticks, mosquitoes, lice, mites (excluding mange mites), biting & sand flies, and adult and immature flea stages (all) year-round treatment is recommended.*”
 - c. On page 10 of the label, revise “*Repellency against fleas, ticks, mosquitoes, lice, mites and sand flies for 4 weeks (30 days)(one month)*” to read “*Repellency against fleas, ticks, mosquitoes, lice, mites (excluding mange mites) and sand flies for 4 weeks*”.
 - d. On page 10 of the label, revise “*Contains the proven effective topical repellent, permethrin (for control of fleas, ticks, mosquitoes, lice, mites and biting & sand flies)*” to read “*Contains the proven effective topical repellent, permethrin (for control of fleas, ticks, mosquitoes, lice, mites (excluding mange mites) and biting & sand flies)*”.
 - e. On page 10, revise “*Kills mites*” to read “*Kills mites (excluding mange mites)*”.
2. Per comment #3 on the Agency review dated October 4, 2010; all references to fire ants must be deleted from the label. On page 12 of the label, revise “*Repels fleas, ticks, mosquitoes, fire ants, biting & sand flies, lice and mites (excluding mange mites)*” to read “*Repels fleas, ticks, mosquitoes, biting & sand flies, lice and mites (excluding mange mites)*”. Alternatively, the claim may be deleted altogether.
3. Per comment #8 on the Agency review dated October 4, 2010; change “*Kills fleas in 6 hours*” to read “*Starts to kill fleas in 6 hours*”. This claim is found on page 6 of the proposed label. Alternatively, this claim may be deleted from the label altogether.
4. Per comment #31 on the Agency review dated October 4, 2010; change “*Kills the vectors that may transmit Lyme disease, Rocky Mountain spotted fever, babesiosis, ehrlichiosis, bartonellosis, hepatozoonosis, leishmaniasis and heartworm disease*” to read “*Kills the listed vectors that may transmit Lyme*”.

disease, Rocky Mountain spotted fever, babesiosis, ehrlichiosis, bartonellosis, hepatozoonosis, leishmaniasis and heartworm disease". This claim is found on the bottom of page 12 of the proposed label. Alternatively, the claim may be deleted altogether.

5. On page 12 of the label, delete "*SVP7 together with heartworm preventative may be helpful in providing an extra layer of protection against possible transmission from feeding mosquitoes that may be carrying heartworm larvae.*" It is not appropriate to reference FDA registered drugs on EPA spot-on labels. In addition, as mentioned in the Agency review dated October 4, 2010, the claim has heightened safety implications.